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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,465	02/07/2005	Matthew H T Bui	306J-000220US	4663

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
08/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,465	BUI ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 21, 2009 has been entered.

2. Claims 1, 5, 7-23 and 26-28 are pending.

Claims 1 and 14 have been amended.

Claims 4 and 24 been cancelled.

Claims 27 and 28 have been added.

Claims 1, 5, 7-23 and 26-28 to the extent the CAIX is a polypeptide are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

4. The rejection of claims 1, 5 and 7-13 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicants' amendment to claim 1.

Claim Rejections - 35 USC § 102

5. The rejection of claims 1, 5, 7-11, 14-16, 18-23 and 26 under 35 U.S.C. 102(b) as being anticipated by Zavada et al./ U.S. Patent number 5,955,075 (issued September 21, 1999/ IDS reference 11 submitted March 31, 2005) is withdrawn in light of Applicants' amendment to claims 1 and 14. However, this instant rejection may be reinstated upon the deletion of the new matter, see pending new matter rejection under 35 USC § 112 set forth on page 5.

6. The rejection of claims 1, 5, 7-11, 14-16, 18-23 and 26 under 35 U.S.C. 102(b) as being anticipated by WO 95/34650 (published December 21, 1995) is withdrawn in light of Applicants' amendment to claims 1 and 14. However, this instant rejection may be reinstated upon the deletion of the new matter, see pending new matter rejection under 35 USC § 112 set forth on page 5.

Claim Rejections - 35 USC § 103

7. The rejection of claims 1, 5, 7-23 and 26 under 35 U.S.C. 103(a) as being unpatentable over Zavada et al./ U.S. Patent number 5,955,075 (issued September 21, 1999/ IDS reference 11 submitted March 31, 2005), and further in view of Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1657, March 15, 2001/ IDS reference 83 submitted March 31, 2005) is withdrawn in light of Applicants' amendment to claims 1 and 14. However, this instant rejection may be reinstated upon the deletion of the new matter, see pending new matter rejection under 35 USC § 112 set forth on page 5.

8. The rejection of claims 1, 5, 7-23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/34650 (published December 21, 1995), and further in view of Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1657, March 15, 2001/ IDS reference 83 submitted March 31, 2005) is withdrawn in light of Applicants' amendment to claims 1 and 14. However, this instant rejection may be reinstated upon the deletion of the new matter, see pending new matter rejection under 35 USC § 112 set forth on page 5.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 5, 7-23 and 26-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. ***THIS IS A NEW MATTER REJECTION.***

Applicants have amended claims 1 and 14 to include section "(c) using the prognosis in the selection and design of a treatment regimen for the subject." Applicants assert "[s]upport for the use of the prognosis in selection and design of treatment regimen is found in paragraph 38", see Remarks submitted July 21, 2009. Applicants have also added claims 27 and 28 and assert support for these claims is found in paragraph 35. The Examiner has reviewed the specification, particularly these sections of the specification noted by Applicants and does not find the support claimed. Section 35 basically notes CAIX levels can be used to predict clinical outcome and identify high risk patients in need of best-fit therapies. Section 38 speaks to identification of CAIX antigen by several art known techniques, particularly immunohistochemical staining. These sections of the specification do not support implementing the renal cell

carcinoma prognosis based on detecting of CAIX in the choice and conception of a treatment regimen. Applicants should delete the new matter or definitively locate support for the amendments to the claims.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1, 5, 7-23 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zavada et al./ U.S. Patent number 5,955,075 (issued September 21, 1999/ IDS reference 11 submitted March 31, 2005), and further in view of Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1657, March 15, 2001/ IDS reference 83 submitted March 31, 2005) and Belldegrun et al./ U.S. Patent Application Publication number 2002/0058041 A1 (published May 16, 2002). Zavada teaches a method of quantitating MN antigen also art known as CAIX located in a patient sample implementing an immunoassay, such as immunohistochemical assays, ELISAS or fluorometric assays, see attached database sheet; column 5, lines 49-column 6, line 3; column 6, lines 47-54; column 36, line 44-column 39, line 35; and Example 13 starting in column 55. Column 4, lines 2-7 addresses the fact that detection of MN antigen is "...prevalent in tumor cells and present sometimes in morphologically normal appearing areas of tissues specimens exhibiting dysplasia and/or malignancy", see column 14,

lines 41-64; and Table 3 in column 58. This detection and resulting positive expression of MN in kidney tissue reads on obtaining a prognosis for the subject and correlating with probability of renal cell carcinoma. While the patent does not explicitly list the percentages referenced in the claims, the disclosure reads on Applicants' active step listed in claim 1, quantifying expressed CAIX and hence reads on a method of aiding in RCC prognosis and correlating the expression data with a probability of RCC prognosis, wherein the quantified CAIX expression data comprises the claimed quantification percentages and correlates with positive responses. The patent does not teach the quantified CAIX expression data in a computer-readable form, wherein there is a programmable computer with a database and an algorithm. Nor does Zavada teach using the prognosis in the selection and design of a treatment regimen, specifically an adjuvant immunotherapy treatment regimen for the subject.

However, Zisman teaches a method of quantifying expressed CAIX in samples from patients with RCC and the data and characteristics of this evaluated population using Stata statistical software, see page 1650, 2nd column, last paragraph of Survival...section and Results. Zisman also teaches the prognostic significance of RCC classification is important and useful in evaluating clinical outcome, directing therapy, determining eligibility for entry into clinical studies, as well as defining a patient's probability of survival, see page 1653, column 1. The disclosed system allows one of ordinary skill in the art to prognosticate, decide the best fit treatment modality and determine survival differences imposed by different histologic types of RCC, see page 1657. Belldegrun teaches treating renal cell cancers expressing a G250 antigenic

marker, see abstract. G250 is art known to be the same as CAIX. Immunogenic preparations and vaccines containing auxiliary substances such as emulsifying agents and adjuvants are added to the said compositions to enhance the effectiveness and stimulation of immune responses, see page 8, sections 0095 and 0100-0103. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to assess the data, determine the best way of treating the patient and implement the computer based program of Zisman. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to assess the data and base a treatment upon results, particularly adjuvant immunotherapy. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in documents that CAIX is a diagnostic marker for tumorigenicity and is prognostic for neoplastic/pre-neoplastic disease, as well as the system of Zisman stratifies and analyzes data for discriminating patient prognosis and can aid in establishing criteria germane to entry in to clinical trials, see patent, column 1, lines 15-25; and column 2, lines 1-9; and the entire Zisman article. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in the documents that CAIX is a diagnostic marker for tumorigenicity and is prognostic for neoplastic/pre-neoplastic disease and RCC is responsive to immunotherapy, see Zavada, column 1, lines 15-25; column 2, lines 1-9; and Belldegrun, section 0238.

11. Claims 1, 5, 7-23 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/34650 (published December 21, 1995), and further in view of Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1657, March 15, 2001/ IDS reference 83 submitted March 31, 2005) and Belldegrun et al./ U.S. Patent Application Publication number 2002/0058041 A1 (published May 16, 2002). The WO document discloses a method of quantitating MN antigen also art known as CAIX located in a patient sample implementing an immunoassay, such as immunohistochemical assays, ELISAS or fluorometric assays, see sequence alignment at conclusion of this rejection; abstract; page 10, line 22-page 11, line 4; page 52, line 26-page 55, line 13. Applicants' claims set forth one active step listed in claim 1 (a), quantifying by immunohistochemical staining or immunoassay expressed human CAIX protein and hence reads on a method of aiding in RCC prognosis and correlating the expression data with a probability of RCC prognosis, wherein the quantified CAIX expression data comprises the claimed quantification percentages and correlates with positive responses. The WO document does not teach the quantified CAIX expression data in a computer-readable form, wherein there is a programmable computer with a database and an algorithm. Nor does said document teach using the prognosis in the selection and design of a treatment regimen, specifically an adjuvant immunotherapy treatment regimen for the subject.

However, Zisman teaches a method of quantifying expressed CAIX in samples from patients with RCC and the data and characteristics of this evaluated population using Stata statistical software, see page 1650, 2nd column, last paragraph of Survival...section and Results. Zisman also teaches the prognostic significance of RCC

classification is important and useful in evaluating clinical outcome, directing therapy, determining eligibility for entry into clinical studies, as well as defining a patient's probability of survival, see page 1653, column 1. The disclosed system allows one of ordinary skill in the art to prognosticate, decide the best fit treatment modality and determine survival differences imposed by different histologic types of RCC, see page 1657. Belldegrun teaches treating renal cell cancers expressing a G250 antigenic marker, see abstract. G250 is art known to be the same as CAIX. Immunogenic preparations and vaccines containing auxiliary substances such as emulsifying agents and adjuvants are added to the said compositions to enhance the effectiveness and stimulation of immune responses, see page 8, sections 0095 and 0100-0103. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to assess the data, determine the best way of treating the patient and implement the computer based program of Zisman. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to assess the data and base a treatment upon results, particularly adjuvant immunotherapy. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in documents that CAIX is a diagnostic marker for tumorigenicity and is prognostic for neoplastic/pre-neoplastic disease, as well as the system of Zisman stratifies and analyzes data for discriminating patient prognosis and can aid in establishing criteria germane to entry in to clinical trials, see patent, column 1, lines 15-25; and column 2, lines 1-9; and the entire Zisman article. One of ordinary skill in the art would have been motivated to do so with a

reasonable expectation of success by teachings in the documents that CAIX is a diagnostic marker for tumorigenicity and is prognostic for neoplastic/pre-neoplastic disease and RCC is responsive to immunotherapy, see the WO document and Belldegrun, section 0238.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
13 August 2009

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643